

REMARKS

The Office Action

Claims 1-3 and 5-9 are pending in this application. Claims 3, and 5-9 are withdrawn from consideration. Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 1 and 2 are also rejected under 35 U.S.C. § 102(b) for lack novelty over Naughton et al. (U.S. Patent No. 5,842,477; hereinafter “Naughton”) as evidenced by Ha et al. (U.S. Patent Application Publication No. 2005/0118714; hereinafter “Ha”). By this reply, Applicant amends claims 1 and 2, and addresses each of the rejections.

Support for the Amendment

Support for the amendment to claim 1 is found in original claim 1 and on page 1, line 19, through page 2, line 2; page 2, lines 16-28; page 7, lines 22-29; and page 20, line 20, through page 21, line 8. Although the phrase “whereby said USSCs regenerate cardiac muscle in said patient and treat said disease” is not present in the specification, *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of 35 U.S.C. § 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. Here, the passages of the specification indicated above clearly indicate that USSCs can be administered to a patient to treat cardiac muscle disease and that USSCs treat the disease because they demonstrate the ability to differentiate into muscle cells. (*In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. (BNA) 465, 467 (CCPA 1978).)

Applicant has amended claim 2 to replace the term “derived from” with the term “obtained from”, which more clearly describes the subject matter sought to be protected. No new

matter is added by the amendment.

Telephone Interview with the Examiner

Applicants wish to thank the Examiner for the telephonic interview of April 25, 2007. Based on the discussion with the Examiner, Applicant believes that the present amendment addresses all of the issues raised by the Examiner in the present Office Action and places the claims in conditions for allowance. If the Examiner does not agree, Applicants respectfully request that the Examiner contact the undersigned by phone in order to resolve any remaining issues in this case.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner states that there is no antecedent basis for the phrase “said patient” in claim 1 (Office Action, p. 2). Applicant has amended claim 1 to recite “[a] method for treating a cardiac muscle disease in a human patient in need of treatment for cardiac muscle disease.” Because claim 1 now provides proper antecedent basis for the term “said patient” the rejection as it applies to claim 1 can be withdrawn.

The Examiner also rejects claim 2, stating that “the metes and bounds of the term ‘derived from’ are unclear...It would be remedial to amend the claim language to use the term ‘obtained from’, which implies a more direct method of obtaining USSCs” (Office Action, p. 3). Applicant has amended claim 2 to replace the term “derived from” with the term “obtained from,” as was suggested by the Examiner. Accordingly, the rejection of claim 2 can now be

withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) for lack of novelty over Naughton as evidenced by Ha. The Examiner states:

Naughton et al teaches a method comprising implanting into a patient a biocompatible, non-living three-dimensional scaffold and at least a source of chondrocyte progenitor cells that includes human mesenchymal stem cells obtained from umbilical cord blood or placenta tissue or umbilical cord blood...The human mesenchymal stem cells obtained at least from umbilical cord blood as taught by Naughton et al. must be positive for the CD13 and CD29 antigens, while negative for the CD14 and CD45 antigens and lack of expression of hyaluronan synthase as evidenced by the teachings of Ha et al. (Office Action, p. 4.)

Applicant has amended claim 1 to clarify that Applicant's method involves the administration of USSCs to a human patient **in need of treatment for cardiac muscle disease**. Naughton only discloses "methods of making and/or repairing cartilage in vivo" (see, e.g., col. 3, lines 60-61). Naughton fails to teach or suggest administering any type of cell, and certainly not Applicant's USSCs, to a human patient for the purpose of treating cardiac muscle disease.¹ Thus, Naughton fails to teach or suggest all of the limitations of claims 1 and 2, as presently amended. Accordingly, the rejection of claims 1 and 2 over Naughton as evidenced by Ha can now be withdrawn.

¹ The Examiner relies on the immunophenotypic characterization of mesenchymal stem/progenitor cells (MSPCs) disclosed by Ha to establish the anticipation of claims 1 and 2 over Naughton. Applicant believes that the Examiner's reliance on Ha to establish the anticipation of present claims 1 and 2 over Naughton is improper because the Examiner has provided no evidence to support his conclusion that Ha's MSPCs, which have the same cell surface markers as Applicant's USSCs (see, e.g., page 2 ¶ [0027] of Ha), are the same as the umbilical cord blood-derived stromal cells of Naughton. Because Applicant can distinguish Naughton on other grounds, this issue has not been addressed in more detail.

CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is requested.

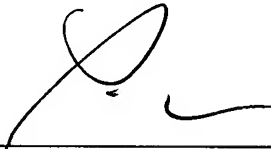
Enclosed is a Petition to extend the period for replying for three months, to and including May 14, 2007, as May 13, 2007, fell on a Sunday, and a check in payment of the required extension fee.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

May 14, 2007



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